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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,273	01/31/2002	Denes V. Agoston	144004.00100	5376

7590 11/15/2005

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/059,273

**Applicant(s)**

AGOSTON, DENES V.

**Examiner**

Janet L. Epps-Ford

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6 and 14-18, drawn to a method for altering the differentiation status of a mammalian cell, classified in class 435, subclass 375.
  - II. Claims 7 and 19 drawn to a cell or cell line, classified in class 424, subclass 93.21.
  - III. Claims 8-9, drawn to a method for isolating a protein, classified in class 435, subclass 6.
  - IV. Claim 10-11, drawn to an isolated protein complex, classified in class 424, subclass 184.1.
  - V. Claims 12-13 drawn to an antibody or kit comprising said antibody, classified in 424, subclass 130.1.
  - VI. Claims 20-33 drawn to a method of treating a disease and a pharmaceutical composition, classified in class 514, subclass 44.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells of invention II can be isolated by a materially different process. For example, the cells having an altered differentiation

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status can be isolated by treating cells with an antibody or inhibitor of the differentiation proteins *p-sept*, *g-sept*, or *n-sept*, since the process of invention I is directed to the administration of nucleic acid decoy inhibitors of these proteins.

4. Invention II is not disclosed as being useful in the methods of inventions III or VI which recite the use of a nucleic acid molecule, and do not require the use of cells or a cell line.

5. Inventions I, III, and VI are all drawn to methods, however each invention method is directed to methods comprising distinct objectives, steps, and outcomes, wherein each invention method would require a separate search and consideration of the prior art.

6. The product of invention IV is not disclosed as useful in the methods of inventions I, III, and VI, each of these methods recite the specific use of a nucleic acid molecule containing the sequence set forth in SEQ ID NO: 1 or 2, and do not refer to the use of protein complex.

7. The product of invention V is not disclosed as useful in the methods of inventions I and VI which recite the use of nucleic acid. Although, the antibody of invention V could potentially be used in methods for alteration of the differentiation status of a cell or a method of treatment, it is clear that there are a variety of other potential uses for the antibody of invention V, for example in an immunoassay for the isolation of the *p-sept*, *g-sept*, or *n-sept* proteins. Moreover, although the antibody of invention V could be used in the method of invention III, as stated above, the antibody also has potential use in methods of treatment.

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8. Moreover, the products of inventions II, V, and IV, are drawn to cells comprising nucleic acid, an isolated protein complex and an antibody, respectively. Each of these products are drawn to chemically and functionally distinct products, which require a separate search and consideration of the prior art.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: (A) The instant claims are drawn to the use of the nucleic acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. (B) Claim 6 recites: p-sept, g-sept, n-sept, nestin, and cycD2. Claim 10 recites p-sept, g-sept or n-sept.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 7-10, 12-17, 19-33 are generic with regard to p-sept, g-sept, n-sept, nestin, and cycD2. Claims 1-33 require either SEQ ID NO: 1 or 2.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

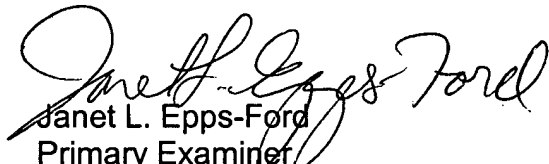
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Janet L. Epps-Ford  
Primary Examiner  
Art Unit 1633

JLE